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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,035	02/24/2004	John N. Voumakis	7867-052-999	3906

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EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/787,035	VOURNAKIS ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-21* is/are pending in the application.

4a) Of the above claim(s) *12-14,16 and 19-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6, 8-11, 15, 17,18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6, 8-21 are pending. Claims 1-6, 8-11, 15, 17, 18 are considered on the merits. Claims 12-14, 16, 19-21 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

Claims 1-6, 8-11 and 18 remain rejected under 35 U.S.C. 102(a) as being anticipated by Okamoto *et al.* [U] in light of US 4,663,289 [A] and US 5,292,524 [D].

The claims are directed to a composition comprising:
a) "biocompatible" poly N-acetylglucosamine polymer and
b) platelets in plasma (PRP).

Dependent claims refer to p-GlcNAc polymer 'fiber", without any definition of 'fiber'. Since p-GlcNAc is a polymer, and a polymer is a chain of similar molecules, they can be said to be a 'fiber' or a thread-like structure in the absence of any length limitations. With regard to the inclusion of calcium chloride in the solution, plasma inherently contains calcium ions and chloride ions as well as magnesium ions. Therefore in the absence of interpretable concentration limitations, the presence of these ions in plasma of platelet-rich-plasma preparations meets the limitations of the claims.

Okamoto *et al.* disclose a composition comprising chitin (purified poly N-acetylglucosamine) in PBS and platelets in plasma (PRP), see Table 1 and Material and Methods, page 644. Because the claimed concentration limitations are indefinite, the reference is considered to meet the limitations as plasma contains calcium, magnesium and chloride ions. Further, in claim 18, isolated platelets are mixed with p-GlcNAc and calcium chloride. Okamoto *et al.* disclose the mixing of isolated platelets with chitin and modified Tyrode's buffer which contains 0.14g/l calcium chloride.

US 4,663,289 in Table 1, shows the concentrations of calcium ion, magnesium ion and chloride ion in plasma in mmoles/L.

US 5,292,524 disclose that Modified Tyrode's Buffer contains 0.14 g/l calcium chloride (col. 16, l. 68).

Response to Arguments

Applicant's arguments filed 10/17/06 have been fully considered but they are not persuasive.

Applicants argue that the modifier "biocompatible" differentiates the instantly claimed component, poly-β-1→4-Nacetylglucosamine from the prior art component, poly-β-1→4-N-acetylglucosamine (chitin) because materials derived from chitin differ widely in terms of their properties and contain contaminants such as covalently bound proteins and are unsuitable for medical use and, therefore, by extension, not biocompatible. Thus, the prior art composition, poly-β-1→4-N-acetylglucosamine (chitin) is distinguished by this term. In evidence the applicant offers Exhibit A, which has no disclosed provenance. That is, it appears to be some sort of handbook written by an undisclosed author or committee at an undisclosed time.

Please see the article by Sathirakul *et al.* where chitin from marine wastes is described as "biocompatible". Clearly those of skill in the art recognize that chitin from marine sources is "biocompatible". Sathirakul *et al.* [U] is a peer reviewed article written in 1996. If applicants' compound, poly-β-1→4-N-acetylglucosamine is distinct from the prior art compound which is also poly-β-1→4-N-acetylglucosamine, as applicants allege, narrowing the claimed composition to exclude the prior art would be advisable instead of merely arguing that the composition is distinct. It is not the arguments which are examined, but the claim language. Please note that a direct comparison with the chitin (poly-β-1→4-N-acetylglucosamine) obtained from Sunfive Co. Ltd. and the instant compound, poly-β-1→4-N-acetylglucosamine obtained from ?, might advance prosecution.

Applicants argue that Okamoto *et al.* do not disclose using stored platelets. However, "stored" is a term of relativity. Storage maybe for one

minute, 1 hour, or days since "stored" is an undefined period of time. The platelets of the reference are prepared and then mixed with chitin. The period between their preparation and use may be term a storage period since the platelets are not prepared in the mixture with chitin; they are added after preparation. Further, the inherent characteristics of the platelets are not modified by the term "stored". Thus a composition comprising "stored" platelets and "unstored" platelets could not be distinguished.

Applicants argue that the concentration of calcium ions in Okamoto *et al.* is not sufficient to induce formation of a gel. However, no objective evidence has been presented, such as a direct comparison of the concentration of calcium ions present in the instant composition to the concentration of calcium ions present in the prior art composition.

In spite of applicant's arguments to substantiate the claimed composition as not anticipated over the cited prior art, insofar as these compositions, instead of being characterized by technical features suitable for the identification of composition, such as concentrations of components, and is imprecisely defined by means of functional features which merely recite the desired result to be achieved, the subject matter is still considered to be anticipated and or obvious by the disclosures of the prior art.

Compositions have components in defined concentrations. Use of convoluted language to obscure the concentrations of the components in the composition of the claims is not persuasive to overcome the prior art. Correct calculations and direct comparisons would be more persuasive and might serve to advance prosecution.

Claim Rejections - 35 USC § 103

Claims 1-11, 15, 17 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,614,204 [B] in combination with US 5,858,350 [C] in light of US 5,292,524 [D] and US 4,663,289 [A].

Claims 1-11 and 18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Okamoto *et al.* [U] in combination with US 5,858,350 [C] in light of US 5,292,524 [D] and US 4,663,289 [A].

Please note that the obviousness rejections have been separated in the interest of clarity and to acknowledge the persuasiveness of parts of applicant's arguments. There is no new ground of rejection.

The claims are directed to a method for accelerating wound healing comprising administering to a wound a composition comprising PRP, p-GlcNAc fiber, wherein the PRP is derived from stored platelets and the composition, per se.

Okamoto *et al.* teach that in early wound healing, blood coagulation plays a very important role because some cytokines are released by platelets during coagulation (Introduction). It is demonstrated that chitin aggregates platelets and subsequently enhances the release of cytokines from platelets (Conclusion). Also disclosed is the composition comprising PRP and chitin, which comprises pGlcNAc. Plasma inherently contains calcium, chloride, and magnesium ions in certain concentrations as disclosed by US 4,663,289 in Table 1.

US 5,614,204 disclose a composition comprising chitin (col. 12, l. 32) and PRP (col. 12, l. 52) used to induce vascular haemostatic occlusion (clotting). The polymer (chitin) is placed in plasma and added to PRP (col. 13, l. 30).

The references lack the disclosure of the use of p-GlcNAc obtained from microalgae which may have distinct characteristics from p-GlcNAc obtained from crustacean shell (chitin).

US 5,858,350 discloses pure poly-β,1-4-N-acetylglucosamine derived from microalgae. The references also discloses that chitin which is a β,1-4-N-acetylglucosamine polymer derived from crustacean shells is not 100% pure β,1-4-N-acetylglucosamine and use of chitin gives rise to unpredictable results

because of the impurities (col. 1 and 2). Thus, this reference teaches the desirability of the use of pure β,1,4-N-acetylglucosamine derived from microalgae in place of β,1-4-N-acetylglucosamine derived from crustacean shells. Microalgae produce fibers of various lengths of β,1-4-N-acetylglucosamine.

US 5,292,524 discloses that Modified Tyrode's Buffer has 0.14g/l calcium chloride (col. 16, l. 68).

US 4,663,289 disclose that plasma contains calcium, magnesium and chloride ions (Table 1).

The substitution of a purified form of β,1-4-N-acetylglucosamine polymer from microalgae for the impure form of β,1-4-N-acetylglucosamine polymer in chitin in the compositions of Okamoto *et al.* or US 5,614,204 would have been obvious when taken with US 5,858,350 which teaches the advantages of such a substitution.

The substitution of the purified form of β,1-4-N-acetylglucosamine polymer from microalgae for the chitin in the method of Okamoto *et al.* for producing a platelet gel would have been obvious when the primary reference of Okamoto *et al.* (Preparation of washed platelet, page 644) was taken with US 5,858,350 which teaches the advantages of using such a purified form of β,1-4-N-acetylglucosamine polymer from microalgae. Please note that Modified Tyrode's Buffer used in Okamoto *et al.* for suspension of platelets has 0.14g/l calcium chloride as disclosed by US '524.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicants continue to argue that no motivation exists for such a substitution of "biocompatible" p-GlcNAc for the p-GlcNAc of the primary references and that the examiner has applied improper hindsight.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants argue that Okamoto *et al.* do not provide a teaching for the use of such as composition. Please note that the claims over Okamoto *et al.* are directed to a composition and the making of the composition, not to the use of such a composition. The motivation for substituting the p-GlcNAc of US 5,858,350 for the p-GlcNAc of Okamoto *et al.* comes from US 5,858,350 which is the secondary reference, where the superiority in terms of reliability of the use p-GlcNAc derived from microalge for the p-GlcNAc from marine sources is clearly taught. Motivation may be found in any of the references used in combination

Applicants argue once again that there is no motivation in US 5,614,204 to produce a composition comprised of "biocompatible" p-GlcNAc and platelets. As explained before, the motivation for such a substitution of p-GlcNAc from a marine source for p-GlcNAc from a microalgal source comes from US 5,858,350 which is the secondary reference where the superiority in terms of reliability of the use p-GlcNAc derived from microalge for the p-GlcNAc in chitin from marine sources is clearly taught. Motivation may be found in any of the references used in combination.

Clarification of the components of the composition and the concentrations thereof might advance prosecution.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651
November 8, 2006